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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,708	10/03/2003	Charlotte A. Kensil	8449-322-999	9606

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,708	KENSIL ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-52,54,58,59 and 61-70* is/are pending in the application.

4a) Of the above claim(s) *54,61 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-52,58,59,63-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 46-52, 54, 58, 59 and 61-70 are pending.

Claims 54, 61 and 62 are withdrawn from further consideration by the examiner 37 CFR 1.142(b) as being drawn to a nonelected species.

Claims 46-52, 58, 59 and 63-70 drawn to a method for enhancing immune response with a composition comprising an antigen, wherein the antigen is a protein, saponin adjuvant, and an excipient, wherein the excipient is a beta-cyclodextrin are under consideration in the instant application.

2. In view of Applicants' response filed 4/21/06, no rejections of record remain.

3. The following new ground of rejections is necessitated by applicant's amendment and addition of new claims filed on 4/21/06.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 46, 49-52, 58, 59 and 63-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,146,632 (of record) as is evidenced in the specification of the instant application on p. 2-3 in view of U.S. Pat. No. 4,727,064, newly cited.

The '632 patent teaches a method of enhancing an immune response with an immunogenic composition comprising antigen from polypeptide, glycoprotein or lipoprotein from bacterial or viral sources (col. 3, lines 46-65, in particular) and QS-21 (col. 1, lines 3-40, col. 3, lines 26-38, Examples1-2, claims 1-8, in particular). The '632 patent further teaches the immunogenic composition can be administered to human (col. 4, lines 31-36, in particular).

In addition, the '632 patent teaches the concurrent administration of antigen and saponin adjuvant (Example 1-2, in particular).

The specification of the instant application on p.2-3 discloses that the QS-21 does not have a long shelf life, and induces irritancy and has toxic effects. As the referenced QS-21 is identical to the claimed QS-21, the referenced QS-21 also has inherent property of short shelf life and induces irritancy.

The '632 patent does not teach beta-cyclodextrin or hyroxypropyl-beta-cyclodextrin as in claims 46, 58 and 59.

However, the 064 patent teaches that the hydroxypropyl-beta-cyclodextrin (HPCD) improves solubility which reduces tendency to cause irritation. The '064 patent further teaches that the HPCD stabilizes wide range of drugs including steroid, exhibits low toxicity and extends shelf life and widely used as an excipient (e.g. additive) (col. 1, lines 25-45, col. 2, lines 36- 60, and claims 1-28, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ the HPCD as an excipient taught by the '064 patent in an immunogenic composition comprising an QS-21 and antigen as taught by the '632 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '064 patent teaches the HPCD adds stability to any drugs and extends shelf life , reduces irritation and exhibits low toxicity (col. 1, lines 25-45, col. 2, lines 36- 60, and claims 1-28, in particular).

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claims 46-52, 58, 59 and 63-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,057,540 (of record) as is evidenced in the specification of the instant application on p. 2-3, 7-10 in view of U.S. Pat. No. 4,727,064, newly cited.

The '540 patent teaches a method for enhancing an immune response with an immunogenic composition comprising a peptide antigen such as gp70 and saponin adjuvant wherein the saponin can be QA-7, 17, 18, 21 and Quil-A (Examples 8-10, 12, in particular) in a human (col. 7, lines 5-6, in particular).

The '540 patent teaches a concurrent administration of antigen and saponin adjuvant (col. 7, lines 14-25 in particular) and addition of any excipient such as inert carrier (col. 8, lines 7-13, in particular).

In addition, the'540 patent teaches the saponin exhibit toxicity (col. 1, lines 31-38, example 14, in particular).

The specification of the instant application on p.2-3 discloses that the QS-21 does not have a long shelf life, and induces irritancy and has toxic effects. As the referenced QS-21 is identical to the claimed QS-21, the referenced QS-21 also has inherent property of short shelf life and induces irritancy. In addition, the referenced QA are identical to the claimed QS (p. 7-10 of the instant specification).

The '540 patent does not teach beta-cyclodextrin or hyroxypropyl-beta-cyclodextrin as in claims 46, 58 and 59.

However, the '064 patent teaches that the hydroxypropyl-beta-cyclodextrin (HPCD) improves solubility which reduces tendency to cause irritation. The '064 patent further teaches that the HPCD stabilizes wide range of drugs including steroid, exhibits low toxicity and extends shelf life and widely used as an excipient (e.g. additive) (col. 1, lines 25-45, col. 2, lines 36- 60, and claims 1-28, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ the HPCD as an excipient taught by the '064 patent in an immunogenic composition as taught by the '540 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '064 patent teaches the HPCD adds stability to any drugs and extends shelf life , reduces irritation and exhibits low toxicity (col. 1, lines 25-45, col. 2, lines 36- 60, and claims 1-28, in particular).

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
July 6, 2006

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